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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,550	10/26/2001	Eldon H. Nyhart JR.	3413-13	3390
30565	7590	02/27/2006	EXAMINER	
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137			THANH, LOAN H	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/045,550	Applicant(s) NYHART, ELDON H.	
	Examiner LoAn H. Thanh	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-65 and 104-140 is/are pending in the application.
- 4a) Of the above claim(s) 107-140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-65 and 104-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>See Office action</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group II in the reply filed on 09/12/05 & 05/23/05 is acknowledged. The traversal is on the ground(s) that the subject matter of the claims have been searched and examined in a divisional application. This is not found persuasive because this application is considered to be a separate application in itself. Further, Applicant is to respond to the restriction to the claims as originally presented at that time. Claims 107-140 were later introduced and further cover subject matter which was not originally presented at the time of the restriction.

Claims 107-140 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 57-65, 104-106 are currently being treated on the merits.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 03/18/02, 04/16/02, 03/25/04 & 06/20/05 were filed before the first office action on the merits.

With respect to the IDS filed 03/18/02, although the IDS was not submitted with the attorneys signature the Examiner considered the IDS since it was originally filed in the parent application.

With respect to the 4,186,745 patent that was filed in the 06/20/05 IDS , it is not considered by the Examiner since the patent number and the Inventor does not match. It is not clear what patent applicant is attempting to submit for consideration. For this patent to be considered, Applicant needs to resubmit the IDS under the rules.

With respect to the IDS submitted 04/16/02 and 03/25/04, the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 57-59,62,64,105-106 are rejected under 35 U.S.C. 102(e) as being anticipated by Altman et al. (US 6,086,582).

Altman et al. disclose a method of providing a compound to a system comprising a catheter having a drug which is releasably captured in the matrix , a source of electrical energy 1052 which is activated to release the drug from the matrix 1060 , a controller which senses electrical activity of the heart and responds by injecting delivery

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of the drug or goes into monitoring mode depending on the sensed electrical activity.

See column 14, lines 7-47 and col.14, line 66 to col. 15, lines 47. With respect to claims 64, Altman et al. disclose the releasing of the drug depends on the sensed electrical activity and as such , it is considered to releasing predetermine amounts of compounds at variable intervals. See column 16, lines 2-8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,086,582) in view of Chupakhin et al. (US 6,028,068) .

Altman et al. discloses the invention as substantially claimed. See above. Altman et al. teach treating the cardiac system or circulatory system of a biological unit with cardiac agents. However, Altman et al. does not disclose the therapeutic agent is anesthetic and the system to be the neurological system. Chupakhin et al. teach 6H-1,3,4-thiadiazin-2-amines drugs used in medicine acting as anesthetics, cardiovascular and hypometabolic agents. Specifically, Chupakhin et al. teach that anesthetic agents act as respiratory and cardiovascular depressants. Further, agents have been identified as having anesthetic and cardiovascular property, which are used in brain and

myocardial infarction. Anesthetics are a drug class which is well known for acting on the neurological system. It would have been obvious to one of ordinary skill in the anesthesia art to substitute the cardiovascular drug of Altman et al. with the 6H-1,3,4-thiadiazin-2-amines which could treat the patient in a life-threatening situation with the properties of the being an anesthetic and cardiovascular agent which act on the circulatory and neurological system.

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,086,582) in view of Donatsch et al. (US 4,789,673).

Altman et al. discloses the invention as substantially claimed. See above. Altman et al. teach treating the cardiac system or circulatory system of a biological unit with cardiac agents. However, Altman et al. is silent to a neurotransmitter as an agent in the neurological system of the biological unit. Donatsch et al. teach serotonin M receptor antagonists for the treatment of pain, migraine, vascular and treatment of heart circulation disorders. Serotonin receptors are located in the nervous system of the GI track, the **heart**, the bladder and the adrenal glands. It would have been obvious to one of ordinary skill in the medical art to substitute the cardiovascular drug of Altman et al. with another cardiovascular drug such as the Serotonin M receptor antagonist of Donatsch et al. in order to treat heart circulation disorders.

Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,086,582).

Altman et al. disclose the invention as substantially claimed. See above. However, Altman et al. is silent to the control signal having a frequency content of less than about 1 Hz. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the frequency to about 1 HZ since it lacks criticality and this parameter is deemed matters of choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Claims 65 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,086,582) in view of Ellinwood, Jr. (US 4,146,029) .

Altman et al. discloses the invention as substantially claimed. See above. Altman et al. teach treating the cardiac system or circulatory system of a biological unit with cardiac agents. Altman et al. teach a controller for releasing an amount of drug at variable intervals. However, Altman et al. is silent to releasing variable amounts of the compound at predetermined intervals or releasing variable amounts of the drug at variable intervals. Ellinwood, Jr. teaches a programmable controller for a medication system . See figures 1-11. Ellinwood, Jr. teaches 1/ sensing , timed evaluation, with decision control, 2/ periodic sensing and screening control , 3/ periodic sensing , data evaluation with dosage control, 4/ periodic sensing, data evaluation and alternate dosage selection , and 5/ sensing , controlled same dosage with different amounts for different conditions. See column 3, lines 9-46, and column 4, lines 39-42. Ellinwood, Jr. further discloses that a large number of variables can be programmed to match both the immediate and changing conditions of a wide range of patient needs. Thus, it would


have been obvious to modify the predetermined amount of the drug and/or the interval time of Altman et al. with variable amounts of drug and/or variable interval times as taught by Ellinwood, Jr. in order to provide a more effective treatment method for the varying need of the patient condition.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


LoAn H. Thanh
Primary Examiner
Art Unit 3763